

## **REMARKS**

### **Status of the Claims**

Claims 1-8, 14-20, 53, and 59-60 are pending. Claims 1 and 2 have been amended as described elsewhere herein. Support for the amendments may be found in the originally-filed specification and claims including, for example, on lines 24-30 of page 6. No new matter has been added by way of amendment. The Examiner is respectfully requested to withdraw the rejections and allow claims 1-8, 14-20, 53, and 59-60.

### **The Rejection Under 35 U.S.C. §112, Second Paragraph, Should be Withdrawn**

Claims 1-8, 14, and 16-18 have been rejected under 35 U.S.C. §112, second paragraph, on the grounds that they are indefinite in reciting that the *Neisserial* strain has been genetically engineered to permanently downregulate the expression of functional gene product from the *lgtB* gene. The rejection is respectfully traversed.

According to MPEP §2173.02, the definiteness of claim language must be analyzed not in a vacuum, but in light of the content of the disclosure, the teachings of the prior art, and the interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. In the present case, the specification teaches various methods of downregulating the expression of a gene. See, for example, lines 24-30 of page 6 of the specification. Accordingly, one of skill in the pertinent art, when interpreting claims 1-8, 14, and 16-18 in light of the prior art and the supporting specification, would be able to determine the area circumscribed by these claims.

Claim 1 has further been rejected on the grounds that the claim does not recite that the bleb preparation is isolated. This claim has been amended pursuant to the Examiner's suggestion.

Claims 4-7 have been rejected under 35 U.S.C. §112, second paragraph, on the grounds that they are indefinite because they depend from claim 3, which recites that the *Neisserial* strain cannot synthesize capsular polysaccharide. The rejection is

respectfully traversed. Claims 5-7 depend from claim 1, not claim 3, and thus the rejection should not apply to these claims. With respect to claim 4, the scope of the claim would be clear to one of skill in the art in the context of the claim set. Claim 3 recites a bleb preparation from a Neisserial strain that cannot synthesize capsular polysaccharide, and claim 4 recites a list of various gene products which may be downregulated to produce the bleb preparation recited in claim 3. Accordingly, the scope of this claim is clear as written.

In view of the above arguments and amendments, all grounds for rejection under 35 U.S.C. §112, second paragraph, have been obviated or overcome. Reconsideration and withdrawal of the rejections are respectfully requested.

The Rejections Under 35 U.S.C. §112, First Paragraph, Should be Withdrawn

Claim 1 has been rejected under 35 U.S.C. §112, first paragraph, on the grounds that the specification fails to provide sufficient enablement for a Neisserial strain that has been genetically engineered to permanently downregulate the expression of a gene product because the specification refers to WO 01/09350 for guidance regarding methods of downregulating the expression of Neisserial gene products. Claims 1-8, 14, and 16-18 have been rejected under 35 U.S.C. §112, first paragraph, on the grounds that these claims lack an adequate written description of invention recited in these claims. In both rejections, the Examiner argues that these techniques taught in WO 01/09350 are essential material that should be included in the present specification. Both rejections are respectfully traversed on the grounds that the techniques for genetically engineering Neisserial strains as recited in WO 01/09350 are not essential material with respect to the present claims.

MPEP §608.01(p) states that essential material includes material that is necessary to describe the claimed invention or to enable any person skilled to make and use the claimed invention. In the present case, claims 1-8, 14, and 16-18 are not directed to techniques for genetically engineering Neisserial strains, but rather to isolated bleb preparations from Neisserial strains with particular genetic modifications. Accordingly, the genetic engineering techniques described in WO 01/09350 are not essential material with respect to the invention recited in these claims.

In the Office Action, it is also argued that claims 1-8, 14, and 16-18 fail to meet the written description requirement on the grounds that the specification does not demonstrate reduction to practice for a large number of species within the genus of *Neisserial* bleb preparations from a *Neisserial* meningococcal strain with an L3 lipooligosaccharide (LOS) immunotype, where the *Neisserial* meningococcal strain has been genetically engineered to permanently downregulate the expression of functional gene product from the *lgtB* gene.

The written description requirement may be satisfied by disclosure of relevant, identifying characteristics to show that the Applicant was in possession of the claimed genus. In the present case, the prior art taught the sequence of the *lgtB* gene from a number of *Neisseria* strains. The prior art also taught methods of downregulating the expression of a gene product of known sequence. Thus, the reduction to practice of *Neisserial* strains engineered to downregulate the expression of *lgtB* found in the present specification (see Examples 3 and 5), combined with the knowledge of *Neisserial lgtB* gene sequences known in the art and the knowledge of one of skill in the art regarding methods of disrupting the expression of known genes demonstrate that the inventors were in possession of the claimed invention at the time of filing.

MPEP §2164.05(a) states, “the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public.” In the present case, techniques for genetically engineering *Neisserial* strains were already known to those of skill in the relevant art, as evidenced by the disclosure of WO 01/09350. The sequence of the *Neisserial* genes recited in claims 1-8, 14, and 16-18 were also known in the art. Accordingly, the bleb preparations recited in these claims meet the requirements of 35 U.S.C. §112, first paragraph.

In view of the above arguments and amendments, all grounds for rejection under 35 U.S.C. §112, first paragraph, have been overcome. Reconsideration and withdrawal of the rejections are respectfully requested.

**CONCLUSION**

All claim rejections being addressed in full, Applicants respectfully request the withdrawal of the outstanding objections and rejections and the issuance of a Notice of Allowance. Should the Examiner have any questions regarding the foregoing, Applicants respectfully request that the Examiner contact the undersigned, who can be reached at (919) 483-1467.

Respectfully submitted,

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